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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/820,183

04/06/2004

Nabil Dib

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04/30/2008

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EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

04/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/820,183	Applicant(s) DIB, NABIL	
	Examiner VICTORIA P. CAMPBELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8 and 10-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8 and 10-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2007 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the second Office Action following the Request for Continued Examination based on the 10/820183 application filed April 6, 2004. Claims 2-8 and 10-22 as amended are currently pending and considered below.

Drawings

1. The drawings are objected to because two figures are currently labeled "5D". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 2-8 and 10-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,989,197 to Avaltroni in view of USPGPub 2002/0026126 A1 to Burdorff et al.

Regarding claims 17-22, 2-4, and 10-12, Avaltroni discloses a medical device, capable of performing either biopsy or injection of tissue, comprising a catheter (4) having a catheter lumen with a proximal and distal end; a needle (3) with a solid pointed end, and a port (6) for receiving biopsy material, which selectively moves to extend from a distal end of the catheter (4) to a first position wherein the pointed end and port (6) are inserted into the body material and retract to a second position wherein at least the port is positioned within the catheter lumen (Fig. 6); a sheath (5) having a sheath lumen through which the catheter (4) is selectively moved; and a driver (12), including means for selectively restricting relative movement (7) between the sheath (5) and the catheter (4).

However, Avaltroni fails to disclose an internal passage within the needle connected to the port. Burdorff et al disclose a biopsy needle (70) with a solid pointed

end (72) having an internal passage (74) and a port (78) in fluid communication with the passage.

Avaltroni and Burdorff et al are analogous art because they are from the same field of endeavor/problem solving area of biopsy devices. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Avaltroni and Burdorff et al before him or her to modify the needle of Avaltroni to include the internal passage of Burdorff et al because doing so would provide an additional volume if larger tissue samples were needed. Therefore, it would have been obvious to combine Avaltroni with Burdorff et al to obtain the invention in the instant claims.

Regarding claims 5-8 and 13-16, Burdorff et al further teach a driver that selectively rotates the needle (Fig. 17B), a positioning sensor (198) on the needle (70), and a second port (22) in fluid communication with the internal passage and first port.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Avaltroni and Burdorff et al before him or her to modify the device of Avaltroni to include the rotator, sensor, and additional port of Burdorff et al because doing so would provide additional control over the device for more precise collection of tissue.

Response to Arguments

4. Applicant's arguments with respect to claims 2-8 and 10-22 have been considered but are moot in view of the new ground(s) of rejection.

Examiner notes that injections could be made using the device of either Avaltroni or Burdorff et al by loading the port with the desired solid or fluid for injection prior to insertion into the tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763